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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,897	11/30/2000	Mindy D. Goldsborough	45858/55672	9257

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/725,897	GOLDSBOROUGH ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 04 May 2004 has been entered.

Priority

2. Acknowledgement is made of applicant claiming benefit of priority under 35 USC 119(e) to 60/175,307, 60/046,219, 60/042629, and 60/122395. It is noted with particularity that

- Papers in the '307 application papers were received on 10 January 2000,
- The '395 application was filed on March 2, 1999, and
- The '629 and '219 applications were filed on 03 April 1997, and 12 May 1997,

respectively.

In order to assert a claim for benefit of priority, copendency must exist between the current application and that upon which a claim of benefit of priority is based. Provisional applications automatically expire after one year. Accordingly, there was no copendency between either the '219 and '395 applications and any subsequently filed application. Accordingly, the claim for benefit of priority to 60/046,219 and 60/042,629 is DENIED.

3. The above-noted '307 application was submitted to the Office on 10 January 2000 but did not receive a filing date. Accordingly, the claim for benefit of priority to the '307 application, and by extension, the '395 application, is DENIED.

4. Accordingly, the effective filing date of the instant application is 30 November 2000.

Specification

5. The substitute specification has NOT been entered as it has been found to contain new matter previous entered and which was objected to in the last Office action.

6. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 49, lines 3-7; and at page 98, lines 3-7:

> **All publications, patents and patent applications mentioned in this specification are indicative of the level of skill of those skilled in the art to which this invention pertains, and are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference."**

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that**

> **material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

7. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

8. At pages 9 through 12 of the response received 04 May 2004 applicant traverses the objection to the specification, and asserts that the present case is distinguishable over the cited art.

9. The above argument has been fully considered and has not been found persuasive for while the original and two versions of substitute specification each provide a bibliographic reference, and in some instances suggest why the document is being incorporated, not one version of the specification identifies with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the

> referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

For the above reasons, and in the absence of convincing evidence to the contrary, thee objection to the specification is maintained.

10. The amendment filed 11 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: That portion of the specification added to marked-up pages 20-89, 98-99, and 102.

11. Acknowledgement is made of where at page 3 of the Office in the Office action mailed 26 March 2002 the specification was objected to as essential subject matter had been incorporated by reference. While applicant has undertaken efforts to bring such subject matter into the present application, that material deemed essential to enabling the present application was not properly incorporated by reference, as the original specification did not "clearly indicate where that material is found in the various documents". See *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679, *supra*.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to argument

12. At pages 14-15 of the response applicant directs attention to pages 98-99, 102, and 103 of the substitute specification, noting that if the amendment e to be deleted, then the application would no longer be in compliance with the sequence rules.

13. As an initial matter, it appears that the presence of multiple versions of a substitute specification may be causing some confusion as to just what is being objected to. The pages that are objected to by the Office are those that are found in the marked copy of the specification submitted on 11 March 2003.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,976,572 (Burgoyne).

16. Burgoyne teaches at length of composition for storage of DNA and RNA, and methods of use. At column 9, fourth paragraph, Burgoyne teaches that RNA that has been immobilized on the matrix is subjected to reverse transcriptase so to synthesize DNA (applicant's cDNA), and

that the cDNA can then be used in a variety of assays, including PCR, LCR, and RFLP. The performance of such methods speaks to the cDNA being double stranded in at least one embodiment.

17. Column 3 first full paragraph, teaches that the "composition of he dry solid medium includes a weak base, a chelating agent, an anionic detergent and optionally uric acid or a urate salt.

18. Column 6, fifth paragraph, teaches a plethora of suitable solid supports, including cellulose, nitrocellulose, hydrophilic polymers including synthetic hydrophilic polymers (e.g., polyester, polyamide, carbonate polymers), polytetrafluoethylene, fiberglass and porous ceramics.

19. Column 6, last paragraph, speaks explicitly of the inclusion of a composition that 'protects against degradation of GM [genetic material; RNA or DNA].'

20. Column 5, second paragraph, teaches a plethora of biological sources from which mRNA can be isolated and stored. Cells, viruses, and preparations from biological materials are specifically identified (claim 16).

21. In view of the above teachings, 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,976,572 (Burgoyne).

Conclusion

22. Rejections and/or objections that appeared in the prior Office action and not repeated hereinabove have been withdrawn.

23. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
09 August 2004